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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,156	10/25/2001	Samuel L. Forusz	70452P001C	3099

8791 7590 06/27/2002

BLAKELY SOKOLOFF TAYLOR & ZAFMAN
12400 WILSHIRE BOULEVARD, SEVENTH FLOOR
LOS ANGELES, CA 90025

EXAMINER	
CHOI, FRANK I	

ART UNIT	PAPER NUMBER
1616	4

DATE MAILED: 06/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/057,156	Applicant(s) FORUSZ ET AL.	
	Examin r Frank I Choi	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sh et with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement filed 10/25/2001 fails to comply with 37 CFR 1.98(a)(1), which requires a list of all patents, publications, or other information submitted for consideration by the Office. Applicant appears to have simply copied the Forms 892 and 1449 which were signed and/or initialed in the parent Application. The Form 892 is used to list documents cited by Examiner in an Office Action and should not be used to list documents to be considered by Examiner for purposes of an IDS. Examiner requires that Applicant submit a list which is unsigned and/or not initialed so that Examiner may considered the documents listed for purposes of the present Application. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Objections

Claim 23 objected to because of the following informalities: "comprises" should be "further comprises". Appropriate correction is required.

Specification

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The second application must be an application for a patent for an invention which is also disclosed in the first application (the parent or provisional application); the disclosure of the invention in the parent application and in the second application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v.*

Performance Contracting, Inc., 38 F.3d 551, 32 USPQ 2d 1077 (Fed. Cir. 1994). The prior application disclosed relatively few examples of acid, i.e. ascorbic acid, malic acid and citric acid, all of which are organic acids. Also, the prior application indicated that the combination of malic and citric acid is used to adjust the pH. As such, equivalence with any acid or acidifier does not appear to have been contemplated by the inventors at the time the parent application was filed or would require undue experimentation in order to determine which other acid or acidifiers would be suitable to make and/or use the invention commensurate in scope with the claims.

This application repeats a substantial portion of prior Application No. 09/365,156, filed 7/30/1999, and adds and claims additional disclosure not presented in the prior application. Since this application names an inventor or inventors named in the prior application, it may constitute a continuation-in-part of the prior application. Should applicant desire to obtain the benefit of the filing date of the prior application, attention is directed to 35 U.S.C. 120 and 37 CFR 1.78.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for acids such as ascorbic acid, malic acid and citric acid and solubilizers such as maltol, maltodextrin and carrageenan and xanthan gum does not reasonably provide enablement for all acids or solubilizers. The specification does not enable any person skilled in

the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The Specification discloses relatively few examples of acid, i.e. ascorbic acid, malic acid and citric acid, all of which are organic acids. Also, in Applicant's example, it is not any single acid, but a combination of malic and citric acid. Finally, the Specification indicates that the combination of malic and citric acid is used to adjust the pH with the pH range being critical (Specification, pg. 13). As such, equivalence with any acid or acidifier does not appear to have been contemplated by the inventors at the time the application was filed. Rather, the amount of the combination of malic and citric acid is limited by pH requirements. With respect to solubilizing the components, the Specification only appears to discuss solubilizing with respect to addition of maltol. It is uncertain from the disclosure, other than what is disclosed as being combined with maltol, i.e. maltodextrin and carrageenan and xanthan gum, what other compounds would be suitable to solubilize the components. As such, it appears that a skilled artisan would be required to do undue experimentation in order to make and/or use the invention commensurate in scope with the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 recites the limitation "isoflavone". There is insufficient antecedent basis for this limitation in the claim as claim 1 does not set forth the same.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-
(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 14-16,20,22 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Liska et al. (US Pat. 6,051,260).

Liska et al. expressly discloses teaches a composition which is mixed in water containing inulin, fructooligosaccharides, a source of panthothenic acid in the form of calcium panthothenate, ascorbic acid, vitamin E, calcium citrate, magnesium citrate, potassium phosphate, Vitamin D3 and Vitamin K (Columns 10,11, Claims 7, 15) falling within the scope of applicant's claims.

Alternatively, at the very least the claimed invention is rendered obvious within the meaning of 35 USC 103, because the prior art discloses products and uses that contain the same exact ingredients/components as that of the claimed invention. See In re Fitzgerald, 205 USPQ 594 (CCPA 1980). See also In re May, 197 USPQ 601, 607 (CCPA 1978); Ex parte Novitski, 26 USPQ2d 1389, 1390-91 (Bd Pat. App. & Inter. 1993).

Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liska et al. (US Pat. 6,051,260) in view of Ohta et al. (US Pat. 5,900,255), Orafti, WO99/07392, Dulebohn et al. (US Pat. 6, 171,633) and Patel et al. (US Pat. 6,150, 399).

Examiner notes the rejection herein does not apply to claimed subject matter which was found to be allowable in US App. No. 09/365,156.

Liska et al. teaches a composition which can be mixed in water or fruit juice containing inulin, fructooligosaccharides, a source of panthothenic acid in the form of calcium panthothenate, ascorbic acid, vitamin E, calcium citrate, magnesium citrate, potassium phosphate, Vitamin D3 and Vitamin K (Column 10, lines 15,16, Claims 7, 15)

Ohta et al. teaches a method of treating osteoporosis comprising calcium and magnesium and a fructo-oligosaccharide (Claims 1-20).

Orafti teaches that inulin stimulates the absorption of magnesium and calcium resulting in improved bone mineral density (Pg. 7).

WO 99/07392 teaches a method of osteoporosis comprising isoflavones, vitamins, for example, vitamin D and vitamin K, and minerals, for example, calcium (Pg. 26, lines 1-20).

Dulebohn et al. teach a beverage containing isoflavones and acids, such as citric and malic acid, and metal ions such as calcium and magnesium which act to stabilize the beverage (See Columns 2, 3). Further, it is taught that gums, such as xanthan gum and carrageenan gum, are used to stabilize the beverage (See Claim 9).

Patel et al. teach that in an isoflavone containing composition, carbohydrates such as maltodextrin and fructooligosaccharides optimize protein stability, mouth feel and palatability of the composition (Column 9, lines 50-68). Further, it is taught that suspension of insoluble

minerals, product stability and mouth feel is further improved by using carageenans (Column 11, lines 5-15).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose a method for increasing bone density. However, the prior art amply suggests the same as it is known that the components, such as inulin, vitamins, minerals, isoflavones are effective in treating osteoporosis. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that the composition would be effective in treating osteoporosis.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ormum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending Application No. 09/365,156. Although the conflicting claims are not identical, they are not

patentably distinct from each other because both claim compositions and methods for increasing bone density containing calcium or calcium and magnesium, an acid up to the equivalent of the calcium or fructooligosaccharides, vitamins, isoflavones and stabilizing agents.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (703) 308-0067. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. José Dees, can be reached on (703) 308-4628. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (703) 308-1235 and (703) 308-0198, respectively.

FIC
June 26, 2002

JOHN PAK
PRIMARY EXAMINER
GROUP 1600

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(424/601 or 424/682 or 424/757 or 514/23 or 514/54 or 514/167 or 514/168 or 514/681 or 514/553 or 514/557 or 514/777 or 514/778 or 514/783) and (calcium or (calcium and magnesium)) and (acid or citric or malic) and (inulin or fructooligosaccharide or fructo oligosaccharide) and (424/601 or 424/682 or 424/757 or 514/23 or 514/54 or 514/167 or 514/168 or 514/681 or 514/553 or 514/557 or 514/777 or 514/778 or 514/783)
2002-06-25
23:32:01

S6590
U
USPT,PGPB,JPAB,EPAB,DWPI,TDBD
(424/601 or 424/682 or 424/757 or 514/23 or 514/54 or 514/167 or 514/168 or 514/681 or 514/553 or 514/557 or 514/777 or 514/778 or 514/783) and (calcium or (calcium and magnesium)) and ((acid or citric or malic) near5 (eq or equiv$10)) and (inulin or fructooligosaccharide or fructo oligosaccharide)
2002-06-25
23:28:39

S6589
U
USPT,PGPB,JPAB,EPAB,DWPI,TDBD
(424/601 or 424/682 or 424/757 or 514/23 or 514/54 or 514/167 or 514/168 or 514/681 or 514/553 or 514/557 or 514/777 or 514/778 or 514/783) and (calcium or (calcium and magnesium)) and ((acid or citric or malic) near5 (eq or equivalent)) and (inulin or fructooligosaccharide or fructo oligosaccharide)
2002-06-25
23:27:56

S6588
U
USPT,PGPB,JPAB,EPAB,DWPI,TDBD
424/601 or 424/682 or 424/757 or 514/23 or 514/54 or 514/167 or 514/168 or 514/681 or 514/553 or 514/557 or 514/777 or 514/778 or 514/783
2002-06-25
23:23:48